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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,116	08/29/2003	Cheorl-Ho Kim	WON-PF-2002-US/P-113	1837
25538	7590	07/29/2004		
CHERYL H AGRIS PHD PO BOX 806 PELHAM, NY 10803			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT 1743	PAPER NUMBER
DATE MAILED: 07/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/652,116	Applicant(s) KIM ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☒ Claim(s) 1-5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. The abstract of the disclosure is objected to because the full meaning for the abbreviation “ART” (assisted reproduction technology) should be included in the abstract. Correction is required. See MPEP § 608.01(b).
3. Claims 1-7 are objected to because of the following informalities: In independent claims 1, 5 and 6, the full meaning for MMP-9 (matrix metalloproteinase 9) should be included for clarification purposes. The preamble of claim 2 is inconsistent with the preamble of independent claim 1 since claim 1 recites a method for predicting pregnancy, and claim 2 recites a method for diagnosing the chances of pregnancy. See this same problem in claim 3. On line 2 of claim 3, the word “follicles” should be changed to the singular form –follicle—since independent claim 1 only recites a single follicle. On lines 1-2 of claim 6, the phrase “protein substrate from MMP-9” should be changed to –protein substrate for MMP-9—in order to make proper sense. In claim 7, the preamble “The diagnostic kit of diagnosing the chances of pregnancy” should be changed to –The diagnostic kit for predicting pregnancy outcome—so as to be consistent with the preamble of independent claim 6.

Appropriate correction is required.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Molecular Probes brochure on the EnzChek Gelatinase/Collagenase Assay Kit.

The EnzChek Gelatinase/Collagenase Assay Kit by Molecular Probes is used to measure the gelatinase or collagenase activity of matrix metalloproteinases (MMPs). The kit contains as a component a protein substrate, which can be digested by an MMP. The protein substrate is gelatin, collagen I or collagen IV. See pages 1-2 of the brochure.

7. Claims 1-5 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for predicting pregnancy outcome in a human female subject undergoing assisted reproductive technology by measuring the activity of matrix metalloproteinase-9 (MMP-9) in the follicular fluid from a follicle of a mature oocyte and predicting from the activity of MMP-9 the probability of establishing pregnancy.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Strauss, III et al (US Patent nos. 5,698,404, 6,140,099 and 5,641,636) who teach that MMP-9 is involved in fetal membrane rupture in a gestative female.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

July 26, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1800 1700